IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA	:	CR No. 11 169S
v.	:	
	:	**In Violation of 18 U.S.C. § 1347,**
	:	**21 U.S.C. §§ 331(a) and 333(a)(2),**
GARY WINNER	:	**and 18 U.S.C. § 1957**

INFORMATION

The United States Attorney charges:

INTRODUCTION

At all times relevant to this Information:

1. Defendant GARY WINNER was a resident of the State of Illinois and the President of Planned Eldercare, Inc. (PE).

2. Planned Eldercare was an Illinois corporation which was a nationwide supplier of durable medical equipment (DME). Planned Eldercare's principal place of business was 330 Lexington Drive, Buffalo Grove, Illinois.

A. THE MEDICARE PROGRAM

1. The Medicare Program Generally

3. Medicare is a federal health insurance program covering people aged 65 and older, as well as persons under age 65 who are blind or disabled. The Medicare program is a health care benefit program, as that term is defined in 18 U.S.C. § 24 and as that term is used in 18 U.S.C. § 1347. Medicare is administered by the Centers for Medicare and Medicaid Services (CMS).

4. The Medicare program includes a voluntary supplemental insurance benefit known as "Part B," which is funded from insurance premiums paid by enrolled Medicare beneficiaries, and from contributions from the federal treasury. Part B covers various outpatient items and services, including durable medical equipment (DME) and other medical supplies.

5. CMS contracts with private insurance organizations, referred to as "carriers" under Part B, to receive, adjudicate, and pay Medicare claims submitted by approved and participating health care providers. These carriers are required to administer the Medicare program according to regulations established by CMS. There are four regional carriers, known as Durable Medical Equipment Medicare Administrative Contractors (DME MACs), who are responsible for processing claims for DME reimbursement.

6. The Part B program requires that beneficiaries bear some of the costs of their care. In general, Medicare covers 80 percent of the reasonable charges for services and equipment. Medicare beneficiaries or any supplemental insurance carriers are responsible for the remaining 20 percent. This remaining 20 percent is typically referred to as the beneficiaries' "copayment" amount.

7. This copayment amount is billed by the provider to the beneficiary.

8. Medicare prohibits the waiver of copayments by providers, practitioners, or suppliers because it results in: a) false claims; b) violations of the anti-kickback statute, 18 U.S.C. § 1320a-7b; and c) excessive utilization of items and services paid for by Medicare. The waiving of copayments means beneficiaries are less likely to complain about receiving products they did not order and it enables providers, practitioners and suppliers to bill Medicare for items the beneficiary did not receive but which were billed to Medicare on his or her behalf.

2. Prohibited Telemarketing

9. Section 1834(a)(17)(B) of the Social Security Act, 42 U.S.C. § 1395m(a)(17), prohibits suppliers of DME from making unsolicited telephone calls to Medicare beneficiaries in an attempt to sell them items covered by Medicare Part B, except in three specific situations: (I) the beneficiary has given written permission to the supplier to make contact by telephone; (ii) the contact is regarding a covered item the supplier has already furnished the beneficiary; or (iii) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months.

10. Section 1834(a)(17)(B) of the Social Security Act, 42 U.S.C. § 1395m(a)(17)(B), specifically prohibits payment to a supplier who knowingly submits a claim generated pursuant to a prohibited telephone solicitation.

3. Medicare Coverage for DME

11. For any item to be covered by Medicare as DME, it must be reasonable and medically necessary for the diagnosis or treatment of illness or injury or improve the function of a malformed body part. In addition, it must be used in the patient's home and must meet the definition of DME.

12. Durable medical equipment is defined as equipment that: (a) can withstand repeated use; (b) is primarily and customarily used to serve a medical purpose; (c) generally is not useful to a person in the absence of an illness or injury; and (d) is appropriate for use in the home. All requirements of the definition must be met before an item can be considered DME.

13. For an item to be covered by Medicare Part B, a written, signed, and dated physician's order and information from the treating physician concerning the patient's diagnosis demonstrating the medical necessity of the DME item must be received by the provider/supplier before a claim is

submitted to the DME MAC. Typically, the prescriptions submitted to beneficiaries' physicians, include, among other things, boxes for the physicians to check affirming that the patient had certain diagnoses. If the supplier bills for an item without first receiving the completed order or sufficient information that coverage criteria for an item has been met, the item is not covered by Medicare Part B. For certain DME suppliers, the physician's written order must be received by the supplier prior to delivery of the item.

14. The Centers for Medicare and Medicaid Services assigns billing codes to medical products and services to be used by suppliers and medical providers when billing Medicare Part B. These codes are contained in the Healthcare Common Procedure Coding System and are commonly referred to as "HCPCS" codes. Each HCPCS code is assigned an allowable charge on a state-by-state basis. The allowable charges are published in a fee schedule.

15. To obtain reimbursement from Medicare under Part B, DME providers like PE submit claims to the regional Medicare carriers on a standardized form, commonly referred to as a CMS-1500 form. These claim forms can be submitted manually or electronically. When submitting claims, the DME provider must state, among other things, the HCPCS code or codes applicable to the product or service provided and the name of the physician who prescribed or ordered the particular service.

16. Typically, in the case of PE, the prescriptions submitted to beneficiaries' physicians, included, among other things, boxes for the physicians to check affirming that the patient had certain diagnoses, such as diabetes and/or arthritis. These boxes are known as the ICD-9 code boxes. The DME products sold by PE typically required a physician's diagnosis of either diabetes or arthritis to obtain Medicare reimbursement. The beneficiary's physician is required to complete the

physician's prescription form. The physician order forms used by PE typically also contained a section entitled "Patient Requested the Following Products."

4. Vacuum Erection Devices

17. Under certain circumstance, the Medicare program covers reimbursement for products referred to as Vacuum Erection Devices (VEDs), for the treatment of organic impotence and/or erectile dysfunction. Medicare regulations require VEDs to be medically necessary and prescribed by a physician.

B. THE FOOD DRUG AND COSMETIC ACT

18. The Food Drug and Cosmetic Act , 21 U.S.C. §§ 301, et seq., (FDCA) defines "interstate commerce" as (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any territory not organized by a legislative body. The FDCA requires producers of drugs and medical devices to register with the FDA. New producers, upon first manufacturing, preparing, propagating, compounding, and processing drugs and medical devices, must immediately register their name and place of business with the FDA.

1. Medical Devices

19. Under the FDCA, a "device" includes an instrument, apparatus, implant, machine or other similar or related article, which is intended for use in the treatment and prevention of disease in man, which does not achieve its primary intended purpose through chemical action within and on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purpose.

20. All medical devices marketed in interstate commerce in the United States fall into

one of three regulatory classes under the FDCA: Class I, which are medical devices subject to the least stringent regulatory requirements under the FDCA; Class II, which are subject to an intermediate level of regulatory requirements; and Class III, which are medical devices subject to the most stringent regulatory requirements. The classification assigned to each medical device is determined by the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of that device for its intended use.

21. Any device that was not in commercial distribution prior to May 28, 1976 is initially classified as a Class III device unless it is shown to be substantially equivalent to a device marketed prior to May 28, 1976. 21 U.S.C. § 360c(f)(1). Class III medical devices cannot be legally marketed in the United States until the manufacturer submits to the FDA a Pre-Market Approval Application and the FDA approves the application. 21 U.S.C. § 360e(a)(2).

22. A Class III medical devices is adulterated if it is required to have an approved Pre-market Approval Application and does not have one in effect.

23. A medical device of any class is misbranded if it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under Title 21, United States Code, Section 360. 21 U.S.C. § 352(o).

24. The introduction or delivery for introduction into interstate commerce of any adulterated or misbranded medical device and the causing thereof violates the FDCA. 21 U.S.C. § 331(a).

2. External Penile Rigidity Devices

25. Pursuant to FDA regulations, external penile rigidity devices are those devices intended to create or maintain sufficient penile rigidity for sexual intercourse.

26. The FDA has classified external penile rigidity devices as Class II medical devices, thus exempting the devices from the Pre-Market Notification requirements of the FDCA. Thus, manufacturers of penile rigidity devices who follow certain recommendations or guidance by the FDA to address certain risks associated with the distribution of such devices prior to introducing their device into commercial distribution in the United States are able to market their device without being subject to the Pre-Market Notification requirements contained in the FDCA.

27. The FDA's exemption of penile rigidity devices from the Pre-Market Approval Notification requirements contained in the FDCA does not include intended uses such as treating erectile dysfunction or impotence. Thus, the marketing of a penile rigidity device for a new intended use such as treating erectile dysfunction or impotence takes that device out from the FDA's exemption for Pre-Market Notification and subjects the device to Class III controls, such as Pre-Market Approval.

Count I

(Health Care Fraud)

28. Paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

B. SCHEME AND ARTIFICE TO DEFRAUD

29. Beginning in 2005 and continuing until in or about December 31, 2008, in the District of Rhode Island, and elsewhere, defendant GARY WINNER knowingly devised and intended to devise a scheme and artifice to defraud, and to obtain money and property from a health care benefit program, by improperly submitting claims for reimbursement to Medicare that falsely and fraudulently represented the medical necessity of DME being ordered on behalf of

beneficiaries.

C. MANNER AND MEANS

1. Prohibited Telemarketing

30. It was part of the scheme and artifice to defraud that defendant GARY WINNER regularly purchased telemarketing leads specifically for English-speaking, non-Hispanic, diabetics over the age of 65. Purchasing telemarketing leads for individuals over the age of 65 ensured that defendant GARY WINNER would obtain the telephone contact information for thousands of Medicare beneficiaries.

31. It was further part of the scheme and artifice to defraud that defendant GARY WINNER, using the telemarketing leads he purchased, instructed PE employees to cold call individuals, including Medicare beneficiaries, in order to sell them DME. At times, defendant GARY WINNER employed 10 telemarketers per day.

2. "At No Cost to You" Sales Approach

32. It was further part of the scheme and artifice to defraud that defendant GARY WINNER instructed PE employees, upon successfully reaching an individual on the phone as a result of a telemarketing call, to inquire if they suffered from diabetes or arthritis. In instructing his employees to inquire if the call recipients suffered from diabetes or arthritis, defendant GARY WINNER knew that the individuals being called likely suffered from diabetes because he had specifically included diabetes as one of the criteria for the telemarketing lead he purchased. In addition, defendant GARY WINNER knew that a majority of individuals over the age of 65 suffer from some form of arthritis.

33. It was further part of the scheme and artifice to defraud that once call recipients

identified themselves as suffering from either diabetes or arthritis, as an inducement for call recipients to provide their Medicare and physician information, defendant GARY WINNER instructed PE employees to next inform the call recipients that PE could provide them with products to help with their ailments "at no cost to you."

34. It was further part of the scheme and artifice to defraud that after explaining that PE could provide products "at no cost to you" and obtaining call recipients' Medicare and physician information, defendant GARY WINNER instructed PE employees to recommend products that could help beneficiaries with their ailments.

3. Billing Medicare for DME Not Ordered or Medically Necessary

35. It was further part of the scheme and artifice to defraud that once PE employees obtained Medicare beneficiaries' agreement to receive certain products, defendant GARY WINNER instructed PE employees to order as many DME products as possible for those beneficiaries without regard to whether beneficiaries actually requested the products or had a medical need for the equipment. In practice, this business policy resulted in PE billing Medicare for thousands of DME products that beneficiaries did not order.

36. It was further part of the scheme and artifice to defraud that defendant GARY WINNER would direct the PE sales force to send beneficiaries "packages" of arthritic supplies regardless of medical necessity, once securing beneficiaries' agreements to receive, or orders for, one piece of DME. Upon being confronted by PE employees who questioned the practice of ordering DME that beneficiaries did not order, defendant GARY WINNER typically responded by saying that "it doesn't cost the client anything as the government is paying for it, and that the government would just print more money, so order more."

37. It was further part of the scheme and artifice to defraud that defendant GARY WINNER responded to beneficiaries who received items that they did not order by stating "If you don't need them, put them under the sink."

4. Waiver of Medicare Copayments

38. It was further part of the scheme and artifice to defraud that defendant GARY WINNER waived copayments for all Medicare patients despite being aware that waiving copayments was prohibited by Medicare. By waiving copayments they otherwise would be responsible for, WINNER induced beneficiaries to accept products they had not ordered and not report WINNER's fraudulent billing to Medicare.

39. It was further part of the scheme and artifice to defraud that defendant GARY WINNER instructed his employees to tell beneficiaries that they should ignore their Medicare explanation of benefits form because PE forgave any "remainder of cost."

5. Vacuum Erection Device

40. It was further part of the scheme and artifice to defraud that one of the products about which defendant GARY WINNER instructed his employees to inform male diabetic beneficiaries was an "erectile pump." Defendant GARY WINNER instructed his employees to falsely inform male diabetic Medicare beneficiaries that the pump "was good for prostate problems" and was "designed to help blood circulation exclusively in males."

41. It was further part of the scheme and artifice to defraud that the erectile pumps that defendant GARY WINNER provided male diabetic beneficiaries were in fact penis enlargers sold under various names such as "The Commando," "the Ramrod," and "the Fireman's Penis Pump" that WINNER had purchased from online stores which sold adult sexual products.

42. It was further part of the scheme and artifice to defraud that upon receiving the penis enlargers from the online sex shops, defendant GARY WINNER instructed his employees to remove the devices from the original boxes which were labeled "penis enlarger," repackage the items in a clear plastic bag, and insert an information sheet which included false medical claims about the item, such as "[c]areful regular use of the pump increases blood flow in the urinary tract and prostate region. The pump also helps with bladder control; urinary flow and prostate comfort . . . ."

43. It was further part of the scheme and artifice to defraud that defendant GARY WINNER billed Medicare for the penis enlargers sold to male beneficiaries and represented that the enlargers were medical devices, i.e. VEDs, designed to treat erectile dysfunction. In fact, as defendant GARY WINNER knew that the penis enlargers that he sold to Medicare beneficiaries and for which he billed Medicare served no medical purpose.

44. It was further part of the scheme to defraud that WINNER purchased the penis enlargers for an average price of $26.00 per item and received, on average, $284 per item in reimbursement from Medicare.

D. EXECUTION OF THE SCHEME

45. Beginning in 2006 and continuing until in or about December 31, 2008, in the District of Rhode Island, and elsewhere, defendant GARY WINNER knowingly devised and intended to devise a scheme and artifice to defraud, and to obtain money and property from a health care benefit program, by improperly submitting claims for reimbursement to Medicare for arthritic packages that falsely and fraudulently represented that beneficiaries and their physicians

had ordered all items within those packages and that the items were medically necessary DME, from which PE received $1,839,847.

All in violation of Title 18, United States Code, Section 1347.

Count 2

(Health Care Fraud)

46. Paragraphs 1 through 44 of this Information are incorporated by reference as if fully restated herein.

47. Beginning in 2005 and continuing until in or about July 31, 2009, in the District of Rhode Island, and elsewhere, defendant GARY WINNER knowingly devised and intended to devise a scheme and artifice to defraud, and to obtain money and property from a health care benefit program, by improperly submitting claims for reimbursement to Medicare that falsely and fraudulently represented that beneficiaries were receiving VEDs and that the VEDs were medically necessary DME, from which PE received $370,305

All in violation of Title 18, United States Code, Section 1347.

Count 3

(Introduction of Adulterated and Misbranded Medical Device Into Interstate Commerce)

48. Paragraphs 1 through 45 of this Information are incorporated by reference as if fully restated herein.

49. The penis enlargers that defendant GARY WINNER marketed and distributed constitute "devices" within the meaning of the FDCA.

50. The penis enlargers that defendant GARY WINNER marketed and distributed had not been reviewed or approved by the FDA for any intended use.

51. Neither defendant GARY WINNER nor PE were registered with the FDA in any capacity as producers, manufacturers, preparers, propogators, compounders, or processors of medical devices.

52. On or about December 26, 2007, in the District of Rhode Island and elsewhere, defendant GARY WINNER with the intent to defraud and mislead, introduced, delivered for introduction, and caused to be introduced and delivered for introduction into interstate commerce, namely from Illinois to Rhode Island, an adulterated and misbranded medical device, namely a penis enlarger, a Class III medical device not approved by the FDA.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

Count 4

(Money Laundering)

53. Paragraphs 46 and 47 of this Information are incorporated by reference as if fully restated herein.

54. On or about May 4, 2007, in the District of Rhode Island and elsewhere, the defendant, GARY WINNER, knowingly engaged in a monetary transaction in criminally derived property of a value greater than $10,000, to wit a transfer of $50,000, which was derived from specified unlawful activity, health care fraud, in violation of 18 U.S.C. §1347.

All in violation of Title 18, United States Code, Section 1957.

FORFEITURE ALLEGATION

(Health Care Fraud)

55. Paragraphs 1 through 52 of this Information are incorporated by reference as if fully restated herein.

56. Pursuant to 18 U.S.C. § 982(a)(7), the defendant, GARY WINNER, shall forfeit to the United States, any and all right, title, and interest in any and all property constituting or derived from any proceeds the defendant obtained, directly or indirectly, as a result of the Federal health care offenses alleged in Counts One and Two of this Indictment, which allege that the defendant submitted false claims for reimbursement to the Medicare Program in violation of 18 U.S.C. § 1347, and any and all property traceable to such property, including and limited to the following accounts up to the amount of $2,210,152:

Account number 88048312934 in the name of Paige Enterprises, LLC located at Vanguard Group, 400 Devon Park Drive, Wayne, PA 19087; and

Account number 915-028991 in the name of Paige Enterprises, LLC located at TD Ameritrade, 4211 South 102nd Street, Omaha, Nebraska 68127.

PETER F. NERONHA
United States Attorney

By: _____
DULCE DONOVAN
Assistant U.S. Attorney

_____
STEPHEN G. DAMBRUCH
Assistant U.S. Attorney
Chief, Criminal Division

Date: 9/28/11